IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

EDWIN R. BANKS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.
	)	
XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,	)	5:20-CV-0565-LCB
	)	
Defendant.	)	

DEFENDANT'S RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR DISCOVERY

I. INTRODUCTION

This case involves judicial review of the denial of Medicare claims for certain months of tumor treatment field therapy ("TTFT") for Plaintiff Banks. The Eleventh Circuit remanded the case to this Court "to make a determination on standing, with consideration of supplemental evidence submitted by the parties as appropriate." *Banks v. Sec'y of Health and Human Servs.,* No. 2011454, 2021 WL 3138562, at *4 (11th Cir. July 26, 2021). On October 12, 2021, the Secretary filed a motion to dismiss (Doc. 65), contending that Banks lacks Article III standing because he has suffered no injury-in-fact that is likely to be redressed by a favorable judicial decision. Banks was not held liable for the denied claims and thus, did not pay anything for the claims. In addition, Banks is no longer using the TTFT device and has not alleged that any claims for TTFT have been recently denied. Banks has therefore suffered no concrete, non-speculative harm.

On October 12, 2021, Banks filed a "Motion for Discovery" (Doc. 66) seeking to require the Secretary to produce the following documents:

> All ALJ and QIC/IRE decisions issued in the last two years (i.e., September 1, 2019–September 1, 2021) in beneficiary appeals that were not fully favorable and were not dismissed on procedural grounds.

Doc. 66 at 8. Banks seeks these documents "to identify other decisions (like [the]

Holt [decision])[1] where beneficiaries were held personally liable, based on a prior denial, even in the absence of an [Advanced Beneficiary Notice]." *Id.* Banks contends that these documents "will directly address the Secretary's criticisms of the Holt decision . . . and demonstrate how the Secretary was actually applying the statutes and regulations, regardless of his arguments in litigation."[2] *Id.* at 8–9. The materials are sought solely to further Banks's unsupported argument that he has standing because he risks future harm, i.e., a future denial of a claim for TTFT.

Banks's motion for discovery should be denied for several reasons. First, discovery is generally not available in actions brought under 42 U.S.C. § 405(g). Second, the Holt decision relied upon by Banks does not support his motion for discovery. Third, the materials sought by Banks are irrelevant to this Court's determination on standing. Finally, the request is overly broad and burdensome, would require hundreds of man-hours to fulfill, and would result in the release of thousands of decisions by Administrative Law Judges (ALJs) and Qualified Independent Contractors (QICs) that contain protected health information of Medicare beneficiaries. The Eleventh Circuit did not instruct the court to permit discovery of any kind, much less broad discovery on issues irrelevant to this court's

[1] The Holt Decision, discussed in Plaintiff's Motion for Discovery (Doc. 66) at 6–8, is a decision by a Medicare Administrative Law Judge which Banks contends demonstrates his entitlement to standing. *See generally id.*

[2] In the alternative, Banks proposed a stipulation that the Secretary did not agree to because it is an incorrect statement of the law. *See* Pl. Mot. for Discovery (Doc. 66) at 9.

determination on standing. *See generally Banks*, 2021 WL 3138562.

II. THE DOCUMENTS REQUESTED BY BANKS

Banks seeks decisions rendered by lower-level adjudicators in the Medicare administrative appeals process. In order to challenge a denial of a Medicare claim, a beneficiary must pursue several levels of administrative appeal before he or she may come before a district court. *See generally* 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.904. First, the beneficiary seeks a redetermination from the Medicare Administrative Contractor. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.920, 405.940. Next the beneficiary seeks reconsideration by a QIC. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). There is a separate QIC, or independent review entity (IRE), for Medicare Part C decisions.[3] The next level of review is a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the record. 42 U.S.C. §§ 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

[3] The Medicare program, consists of four main parts: Part A, which generally authorizes insurance payments for covered care provided by hospitals and other institutions or agencies as set forth in the statute, (42 U.S.C. §§ 1395c to 1395i-5, 42 C.F.R. § 409.61(b)); Part B, which authorizes supplemental medical insurance for covered physician services and certain other medical benefits, (42 U.S.C. §§ 1395j to 1395w4); Part C, which authorizes beneficiaries to obtain covered services through Health Maintenance Organizations and other "managed care" arrangements rather than through original Medicare Part A and B, (42 U.S.C. § 1395w-21 to 1395w-28); and Part D, which extends partial coverage for prescription drugs to Medicare beneficiaries (42 U.S.C. § 1395w-101(b)). This case involves a Part B claim for coverage of the TTFT device.

The administrative process ends in a review of the ALJ's decision by the Medicare Appeals Council ("Council"). 42 U.S.C. §§ 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. If the Council does not render a decision within a specified time frame, a beneficiary may request elevation of his appeal to district court. 42 C.F.R. § 405.1132. The Council's decision (or the ALJ decision, if there is no review by the Council) represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136. Plaintiff has requested decisions rendered by ALJs and QICs, which are not binding in future cases and may ultimately be reversed at a higher level of review.

III. ARGUMENT

Federal Rule of Civil Procedure 26(b)(1) allows for discovery "regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). Proportionality considerations include "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). On motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines

that the proposed discovery is outside the scope permitted by Rule 26(b)(1). Fed. R. Civ. P. 26(b)(2)(C).

For the reasons outlined below, Banks's motion for discovery should be denied.

A. Discovery Is Not Available Under 42 US.C. § 405(g).

Judicial review in this case is authorized by 42 U.S.C. § 405(g) (made applicable to Medicare by 42 U.S.C. § 1395ff(b)). Section 405(g) states, in pertinent part, that:

> [t]he court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing. The findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive . . . .

42 U.S.C. § 405(g). The prescriptions contained in this provision are straightforward. First, § 405(g) directs that the court's review is done on the basis of "the pleadings and transcript of the record." *Id.* Furthermore, § 405(g) prescribes the powers of the reviewing court: the court may enter a judgment that "affirm[s], modif[ies], or revers[es] the decision of the [Secretary] . . . ."

Evidence outside of the administrative record is generally not admissible in reviewing an agency action pursuant to 42 U.S.C. § 405(g). *Lovett v. Schweiker*, 667 F.2d 1, 2 (5th Cir. 1981) ("[T]he Act directs the court to enter its judgment only upon the basis of the pleadings and the transcript of the record. 42 U.S.C. § 405(g). No

evidence external to the administrative record is generally admissible in reviewing an administrative action pursuant to 42 U.S.C. 405(g).”). In conducting its review under § 405(g), the court “may only scrutinize the record.” *Leggett v. Chater*, 67 F.3d 558, 564 (5th Cir. 1995) (citations omitted).

The Eleventh Circuit has recognized that discovery in cases involving judicial review of an agency’s administrative record is generally not permitted, absent circumstances not present here. “Though certain circumstances may justify the district court going beyond the administrative record, it is not generally empowered to do so.” *Alabama-Tombigbee Rivers Coalition v. Kempthorne*, 477 F.3d 1250, 1262 (11th Cir. 2007). This “principle reflects the recognition that further judicial inquiry into executive motivation represents a substantial intrusion into the workings of another branch of Government and should normally be avoided.” *Dep’t of Commerce v. New York*, --- U.S. ---, 139 S. Ct. 2551, 2573 (2019) (quotation marks and quotation omitted). The district court may order discovery beyond the administrative record only where there is “a strong showing of bad faith or improper behavior” by the agency. *Id*. at 2573–74 (quotation marks and quotation omitted).

There has been no showing, nor even an allegation, of bad faith or improper behavior by the agency in this action. Banks’s motion for discovery should thus be denied because it is not permitted by 42 U.S.C. § 405(g) or by Eleventh Circuit precedent construing that statute.

B. The Holt Decision Does Not Support Plaintiff's Request for Discovery.

In his argument to the Eleventh Circuit, Banks sought to have the court take judicial notice of an unrelated decision by ALJ Holt that found a different Medicare beneficiary liable for payment of a denied claim (Holt Decision I). *Banks v. Sec'y of Health and Human Servs.*, No. 21-11454, *Plaintiff-Appellant's Motion for Judicial Notice* (attached hereto as Doc. 69-1). Banks contended that standing exists in this case based on the ALJ's holding in the unrelated Holt Decision I.[4] The Secretary objected to Banks's motion for judicial notice, and objects to judicial notice of the Holt decision in this Court as well, for the reasons set forth herein and in *Banks v. Sec'y of Health and Human Servs.*, No. 21-11454, *Defendant-Appellee's Response to Motion for Judicial Notice* (attached hereto as Doc. 69-2). Notably, Banks failed to disclose before the Eleventh Circuit and before this Court in other briefing that Holt Decision I was vacated by the Medicare Appeals Council (MAC), in a decision attached hereto as Doc. 69-3.

Regardless, Holt Decision I is arguably irrelevant here. After remand, Banks attached to the motions presently before the Court a *different* decision by

[4] Holt Decision I found the beneficiary financially responsible not because of a prior ALJ decision, but rather because of a "letter written by the Beneficiary appealing Medicare's denial of his physician's authorization request for coverage of [TTFT] using the Optune system." Holt Decision I did not discuss the beneficiary's liability in the context of § 1395m(j)(4), which requires durable medical equipment suppliers to not only provide advance notice of non-coverage but also obtain a written agreement in advance from the beneficiary agreeing to pay in the event Medicare coverage is denied. 42 U.S.C. § 1395m(j)(4), incorporating 42 U.S.C. § 1395m(a)(18)(A)(ii).

Administrative Law Judge Holt to support his motion for discovery and brief on standing. (Holt Decision II). *See generally* Docs. 66, 66-1, 67, 67-1. Banks contends that Holt Decision II supports his standing argument because the beneficiary was held liable for the costs of the TTFT device, even in the absence of an Advanced Beneficiary Notice. Pl. Mot. for Discovery (Doc. 66) at 7. However, that is not what ALJ Holt held in Holt Decision II. Instead, ALJ Holt found that

> [t]he casefile did not contain any evidence of the actual notice [of non-coverage], or the Advanced Beneficiary Notice documented referenced in the Service Agreement that was provided to the beneficiary. Without evidence of the document or its language contained in the record, the Beneficiary did not know, nor was the Beneficiary reasonably expected to know, that the item at issue was non-covered.

Doc. 66-1 at 12. ALJ Holt further stated that "the Supplier is liable for the non-covered items." *Id.* at 13. However, in the Conclusions of Law section of the decision, ALJ Holt stated that "[t]he Beneficiary is liable for the non-covered items." *Id.* at 13.

Banks has also failed to disclose that the beneficiary and Novocure appealed Holt Decision II to the MAC, which then addressed the discrepancies within the ALJ's decision and held that "the supplier remains financially responsible for the non-covered costs." MAC Decision in ALJ Appeal No. 3-8473385300 (attached as Doc. 69-4) at 7.[5] The Council also addressed the apparent inconsistency in ALJ

[5] Citations to this MAC decision refer to the ECF pagination, not the document's internal pagination.

Holt's order:

> In the Conclusions of Law the ALJ stated that the beneficiary was liable for the non-covered costs; however, this appears to be a scrivener's error, ALJ Decision at 12. In the immediately preceding analysis, the ALJ found the record did not contain evidence that the beneficiary had notice of non-coverage and further found the supplier had constructive notice of non-coverage, holding the supplier liable for the non-covered items.

Id. at 3 n.1.

Thus, Holt Decision II does not support Banks's contention that he is subject to future liability for TTFT claims and, regardless, the Holt Decision was not the final agency decision in that matter. Thus, it holds no legal significance at all.

C. The Requested Discovery Is Not Relevant to this Court's Determination of Standing.

Relevance in the context of discovery "has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter [*sic*] that could bear on, any issue that is or may be in the case." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978). Nevertheless, "discovery, like all matters of procedure, has ultimate and necessary boundaries." *Akridge v. Alfa Mutual Ins*, 1 F. 4th 1271, 1277 (11th Cir. 2021) citing *Taylor v. Hickman*, 329 U.S. 495, 507 (1947). "These limitations necessarily arise when . . . the inquiry touches upon the irrelevant." *Id*.

The lower-level, non-final administrative decisions sought by Banks are not relevant to this Court's determination of standing. Banks contends that the requested

discovery is relevant and necessary to rebut the Secretary's argument that Banks has not suffered an injury in fact sufficient to show standing. However, Banks's assertion that future claims may be denied based on the denied claims in this matter is merely speculative and is not supported by Medicare law and regulations. Banks contends that the requested materials will reveal that the Secretary's position is a "mere litigation position." Pl. Mot. (Doc. 66) at 10. Banks's asserted basis for the relevancy of these materials fails for at least three reasons.

First, the D.C. Circuit has emphasized its "well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions." *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (citing cases). Instead, "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency." *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1040 (D.C. Cir. 2008); *see, e.g.*, *Freeman v. U.S. Dep't of the Interior*, 37 F. Supp. 3d 313, 344–45 (D.D.C. 2014) (finding that "unappealed" ALJ rulings could not estop the United States because such rulings were not binding on the agency or even on other ALJs, and noting that the lack of appeal did not "elevate them to the level of a binding final agency action"); *Thomas Jefferson University v. Shalala,* 512 U.S. 504, 517 (1994) (holding that "the mere fact" that a Medicare contractor . . . may have allowed reimbursement . . . for [certain] costs that appear to have violated the anti-distribution clause does not render the Secretary's

interpretation invalid.").

The decisions of lower-level adjudicators (i.e., the ALJ, QIC and IRE) which Banks seeks to discover are not binding on Banks and are not final decisions of the Secretary. The Secretary is not bound by lower-level administrative decisions. *See Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (finding that the Secretary could not have departed from prior precedent because there were no Council-level decisions finding that the device at issue was "reasonable and necessary" or "safe and effective"). "Nowhere does any policy or regulation suggest that the [Council] owes any deference at all to—much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties merely because they pertain to the same device." *Almy*, 679 F.3d at 310. Indeed, ALJ decisions are not even binding upon lower levels of administrative review, such as the QIC level of review. *See* 42 C.F.R. § 405.968(b)(1) (omitting ALJ decisions among the rulings that bind the QIC). *See generally Heckler v. Ringer*, 466 U.S. 602, 607–08 (1984) (distinguishing between ALJ- and Council-level decisions that "applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

In *Almy*, a plaintiff asserted that decisions of the Council denying coverage for a particular medical device created a policy of denying treatment for that device.

679 F.3d at 299. The Fourth Circuit disagreed, noting that "[t]he Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect. . . . The purported 'policy' in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage." *Id.* at 303. Likewise, in this case, Plaintiff has attempted to elevate non-precedential ALJ opinions into binding coverage rules that would "'stultify the administrative process.'" *See Almy* (quoting *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 202 (1947)). He cannot succeed because the decisions he seeks cannot bind the Secretary and have no precedential effect.

Second, Medicare coverage determinations and findings of beneficiary liability are made based on the specific facts of each claim. The decisions sought by Banks will involve different beneficiaries, each with different medical diagnoses, claims, and medical history. The decisions would not be illustrative to the Court's determination of standing based on a future harm to the Banks.

This is particularly true here, where there was a change in coverage for TTFT after the claim denial at issue in this case. The ALJ decision appealed by Banks was issued under the 2015 Local Coverage Determination (LCD), which categorically denied TTFT coverage and is no longer effective. Effective September 1, 2019, the LCD was revised to permit TTFT coverage for newly diagnosed glioblastoma multiforme (GBM) (the kind of brain cancer suffered by Banks) and continued

coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. AR (Doc. 38)[6] at 1286–87. This very specific scenario further differentiates the Banks decision from other unrelated QIC/IRE and ALJ decisions. It also belies Banks's claim that he is at risk future harm, i.e., a denial of a future TTFT claim based on the denial at issue in this case.

The Seventh Circuit recently found that the change in the LCD for coverage of TTFT foreclosed a beneficiary's argument for standing based on imminent harm. *Prosser v. Becerra*, 2 F.4th 708, 715–16 (7th Cir. 2021) ("Most fatal to Prosser's imminent injury argument, however, is the Medicare program's own recent activity. The recently revised LCD L34823, effective as of September 2019, provides that TTF therapy is presumed reasonable and necessary for the treatment of glioblastoma. At this point, then, we have no facts before us suggesting that Prosser is at imminent risk of being denied coverage."). Further, as discussed in the Secretary's Response in Opposition to Plaintiff's "Brief re: Standing" (Doc. 70), filed contemporaneously herewith, Banks's claim of future harm is non-existent because **Banks is no longer using the TTFT device**. *See* Pl. Mot. for Discovery (Doc. 67) at 14 n.10 (Banks's counsel states he is no longer using the TTFT device); Response in Opp. to Pl. Br. re: Standing (Doc. 70) at 9–11 (explaining that Banks's discontinuation of the TTFT

[6] As in the Secretary's Motion to Dismiss (Doc. 65), Citations to "AR (Doc. 38)" followed by a number refer to pages of Certified Administrative Record, attached as Exhibit C to Appellee's June 15, 2020, Notice of Filing Under Seal (Doc. 38).

device means that he cannot show imminent future injury, with the result that he cannot show standing).

Third, and finally, the Court need not consider irrelevant lower-level administrative decisions to determine standing here. The Secretary's position is supported by the Medicare statute and the specific facts of this case. Banks's argument that he has standing in this case is based upon his position that he has lost his Medicare "mulligan" under 42 U.S.C. § 1395pp.[7] However, Banks's assertion that he risks future liability under 42 U.S.C. § 1395pp is without merit.[8] Section 1395pp applies to situations where Medicare pays one time for a non-covered item when *both* the supplier and beneficiary could not have known that Medicare would deny a claim. That is not what happened here; instead, the supplier was found liable

[7] For the benefit of the Court, what Banks calls the "mulligan" refers to an outcome that may result from the dictates of 42 U.S.C. § 1395pp. Thereunder, even if coverage for a device or service is denied, Medicare will still pay for the device/service if neither the beneficiary nor supplier knew, or reasonably should have known, that the claim would not be paid. *Id.* at § 1395pp(a)(2). This statute is what Banks references as the "Medicare 'mulligan' provisions of 42 U.S.C. § 1395pp(a)" and, specifically, the one-time payment contemplated thereby is what Banks references as the Medicare "mulligan." *See* Pl. Mot. for Discovery (Doc. 66) at 4; Pl. Br. (Doc. 67) at 3, 12–16. After receiving the one-time "mulligan" payment, the statute provides that "thereafter" the beneficiary will be charged with such knowledge and no longer qualify for payment under the provision. 42 U.S.C. § 1395pp(a)(2); *see also* 42 C.F.R. § 411.404(b) (beneficiary deemed to have knowledge).

[8] Banks misrepresent the Medicare Claims Processing Manual by selecting a snippet from a full-page flowchart. Pl. Mot. for Discovery (Doc. 66) at 5. In fact, that flowchart gives the contractor discretion to determine whether the beneficiary's knowledge *may* be established due to notice of a recent claim denial for the same item or service, and, if not, instructs the contractor to determine if the supplier is liable. Medicare Claims Processing Manual, ch. 30 § 30. Banks also cites the general beneficiary knowledge requirement, rather than the knowledge requirement applicable to DME suppliers. *See* Pl. Mot. for Discovery (Doc. 66) at 5 (citing § 30.1).

for the charges for TTFT. Banks mistakenly contends that he has lost this one-time payment opportunity, or Medicare "mulligan."

Banks's argument also ignores the language in § 1395pp(b), which states that "in the case of *comparable situations* arising thereafter with respect to such individual, he shall, by reason of such notice . . . be deemed to have knowledge that payment cannot be made for such items and services." 42 U.S.C. § 1395pp(b) (emphasis added). The knowledge requirement is applied "on a case by case basis." Medicare Claims Processing Manual § 30.1. Here, there was a radical change between the 2015 LCD, which categorically denied coverage for TTFT, and the current LCD, which provides for coverage if certain requirements are met. "It is speculative, and indeed quite unlikely, that an ALJ would deem [plaintiff] to have knowledge that his future TTFT claims will be denied given the change in the 2019 LCD and the current lack of a 'comparable situation' within the meaning of Section 1395pp." *Wilmoth v. Azar*, 2021 WL 681118 at *4 (N.D. Miss. Feb. 22, 2021).

Additionally, Banks' concern is mitigated by Medicare's statutory scheme related to advance notice. Medicare requires that medical equipment suppliers provide the beneficiary with advance notice of non-coverage—generally an Advance Beneficiary Notice—and an agreement by the beneficiary to pay if coverage were denied before a beneficiary will be liable for a denied claim. 42 U.S.C. §§ 1395m(a)(18)(A)(ii), 1395m(j)(4); 1395u(b)(3)(B)(ii); *see Prosser*, 2

F.4th at 711 ("Medical device suppliers—as opposed to healthcare providers in general—bear an additional burden should they wish to shift the risk that coverage may be denied; they must obtain a written agreement by the patients that she will individually bear the cost of the coverage denial."); Medicare Claims Processing Manual, Ch. 30 § 30.1 (for DME suppliers, beneficiary knowledge must be evidenced by a signed written notice and agreement to pay personally in case of a denial). Thus, beneficiaries are further protected from liability for non-coverage of durable medical equipment. This is true even if the claims are on an assigned basis. 42 U.S.C. § 1395u(b)(3)(B)(ii) (assignment agreement transfers to the supplier the beneficiary's right to bill and receive Medicare payment, but the supplier agrees "not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of" § 1395y(a)).

Banks's request for discovery is based upon a flawed analysis and incorrect interpretations of Medicare law. Banks's request also ignores that the facts have significantly changed since his claims were denied under the retired LCD, and Banks has not alleged that his claims have been denied under the new LCD. Further, Banks is no longer using the TTFT device. Under these facts, the Court should not allow Banks to conduct broad discovery of Agency documents that are irrelevant and unnecessary to this Court's determination of standing.

D. The Discovery Request Is Overly Broad and Burdensome.

In considering a request for discovery, this Court should determine "whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). The burden to respond to Banks's requested discovery clearly outweighs any benefit, and the request is overly broad.

Banks seeks the following:

- 5,115 ALJ decisions (Declaration of McArthur Allen (Doc. 69-5) ¶¶ 4–5);
- 36,385 QIC decisions (QIC Letter and Data Summary (Doc. 69-6) at 2); and
- more than 142,000 Part C IRE decisions (Medicare Part C QIC Reconsideration Data for 2020 (Doc. 69-7) at 5, 115, 124).[9]

None of these decisions have any bearing whatsoever on the standing issue before the Court. Further, there is no mechanism to download these decisions all at once; instead, each decision will have to be identified and then individually downloaded by an employee of the Department of Health and Human Services (HHS) Headquarters Appeals Policy and Operations Division (APOD) or the QICs, taking

[9] The undersigned counsel, despite working in conjunction with counsel for Medicare, was not able to determine the number of beneficiary Part C QIC/IRE decisions for the requested time period by the date of this filing. Publicly available reports issued by the Part C IRE show that for 2020, the IRE issued 90,821 partially favorable and unfavorable decisions; 23,704 partially favorable and unfavorable decisions for 2021 Quarter 1; and 27,971 partially favorable and unfavorable decisions for 2021 Quarter 2. Exhibit 5 at 5 (2020), 115 (2021 Q1), 124 (2021 Q2). These reports are available at https://www.medicareappeal.com/Researchers-Data. The Secretary will supplement this information as it becomes available.

those employee off their normal duties. Allen Decl. (Doc. 69-5) ¶¶ 7–8; QIC Letter and Data Summary (Doc. 69-6) at 1. There are only four legal administrative staff members in APOD. Allen Decl. (Doc. 69-5) ¶ 9. The Chief Administrative Law Judge for the Office of Medicare Hearings and Appeals estimates that, for the ALJ decisions alone, it would take the entire APOD administrative staff approximately six weeks to compile the requested ALJ decisions, or nearly 1,000 hours of work. *Id.* ¶¶ 1, 11. The APOD employees who would be tasked with responding to the request would be taken off their regular duties processing ALJ appeals for weeks, delaying the resolution of untold numbers of beneficiary appeals.[10] *Id.* ¶ 12. Additional employees at the QICs and IRE would also be required to download tens of thousands of decisions. *See generally* Doc. 69-6, Doc. 69-7.

Moreover, the thousands of decisions Banks requests each contain medical information of a Medicare beneficiary, including their name, claims information, medical diagnosis, a truncated Medicare number, and, possibly, tax information.[11]

[10] In addition, OMHA is complying with a November 1, 2018 mandamus order from the United States District Court for the District of Columbia in *American Hospital Ass'n v. Becerra*, No. 14-cv-851, to meet certain annual backlog reduction targets and to eliminate the backlog entirely by the end of fiscal year 2022. Reassigning legal administrative staff to prioritize this discovery impacts OMHA's backlog reduction efforts. Allen Decl. (Doc. 69-5) ¶ 13.

[11] The Secretary maintains that a protective order should be put in place should he be required to release these documents. The Court may issue a protective order upon a showing of "good cause." Fed. R. Civ. P. 26(c)(1). In this case, the possibility of disclosure of protected health information places third parties at risk. *See* Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, 45 C.F.R. pts. 160, 164; Privacy Act of 1974, 5 U.S.C. § 522a, thus demonstrating the existence of good cause.

Allen Decl. (Doc. 69-5) ¶ 15. These data elements are entitled to protections because their unauthorized disclosure could cause harm to the associated individual. *Id.* Accordingly, any reproduction of the requested decisions outside of the normal appeals process creates an additional risk of potential breach and consequent harm. *Id.* Alternatively, it is expected that most responsive documents would need heavy redactions pursuant to HHS's obligations under 5 U.S.C. § 552a, further adding to the considerable administrative burden. *Id.* All of this information would have to be redacted manually. *See id.*

The substantial burden that the production of these documents would place on HHS far outweighs any benefit Banks would receive from the requested documents. Indeed, Banks would receive no benefit from the requested documents because, as discussed *supra*, they do not support his argument for standing. The request is also overly broad. The requested decisions will include appeals under Medicare Parts A, B, C, and D, as well as Medicare Secondary Payer and Medicare entitlement and premium appeals, and include a wide range of benefit types, each of which implicates a specific statutorily-defined benefit category, set of coverage rules, set of payment rules, and liability implications, none of which are germane to Plaintiff's request. *Id.* ¶ 14.

A denial of Banks's motion for discovery would not thwart the purpose of the Eleventh Circuit's remand, as he contends. The Eleventh Circuit did not direct the

court to permit broad discovery on issues irrelevant to this court's determination on standing. *See Banks*, 2021 WL 3138562, at *4. As discussed, the documents requested by Banks will not assist this court in determining whether Banks has standing to bring this action.

IV. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court deny Banks's motion for discovery.

Respectfully submitted,

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